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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,018	06/25/2001	Hans O. Ribi	SEGA.004.01US	2628

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RAE-VENTER LAW GROUP, P.C.  
P.O. BOX 1898  
MONTEREY, CA 93942-1898

[REDACTED] EXAMINER

BENNETT, RACHEL M

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER  
1615

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/892,018	<b>Applicant(s)</b> RIBI, HANS O.
	<b>Examiner</b> Rachel M. Bennett	<b>Art Unit</b> 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 02 December 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-84 is/are pending in the application.

4a) Of the above claim(s) 5,26-28,32,34-37 and 43-84 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4,6-25,29-33 and 38-42 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I in Paper No. 7 is acknowledged. While applicants have amended claims 32 and 34 to depend from claim 1, the claims are still drawn to a food coating, whereas the other claims are drawn to a diacetylenic compound dispersed within the ingestible. Therefore, claims 32 and 34 will not be included in Group I. Claims 1-4, 6-25, 29-31, 33, 38-42 will be examined. The requirement is still deemed proper and is therefore made FINAL.

### *Double Patenting*

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 21, 22-23, 30, 31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 7-8, 10, 12-13 of copending Application No. 09/602001. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4, 6-7, 15-20, 24-25, 29, 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6, 11, 14-15 of copending Application No. 09/602001. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to ingestible diacetylenic compounds wherein the ingestible is a solid or liquid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### *Specification*

#### *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 6-14, 15-18, 20-25, 31, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ma Zhanfang et al. (Acta Physico-Chemica Sinica).

Zhanfang discloses color changeable vesicles of polydiacetylenic matrix incorporating glycolipid based on physical force. Glycolipid was successfully inserted into color changeable

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TCDA/DGG and PCDA/DGG polydiacetylene vesicles based on physical force rather than covalent bonding. The effects on polymerization of diacetylene and the change of the polymer vesicles' color due to the relative quantity of glycolipid versus diacetylene molecules are also disclosed. The experimental results demonstrated that this approach is available and the color changeable property of such polydiacetylenic vesicles was not affected due to the incorporation of glycolipid. This provided a simple and useful method of functionalizing the polymer vesicles for their wide application (see abstract). Vesicles possess a closed bimolecular-layer membrane structure to that of biological membranes, and they have extraordinary advantages for simulating biological membrane structure. Such materials have similar sizes to colloidal particles and the surface property of the membrane can be easily controlled, while having a relatively greater transport volume and biocompatibility. Therefore, vesicles have very significantly meaningful applications with respect to the role they could play in many fields including transporting drugs, gene therapy, chemotherapy of cancers, molecular recognition, preparation of ultrafine particles, and controlling reaction properties. Among many polymers resulting from polymerizable surfactant monomers, those having diacetylene structure have many unique properties. One of the characteristics is they can change their own colors when there is a change in temperature, pH, mechanical strength or solvent in the environment. Such a unique optical property of polydiacetylene could make polydiacetylene lipids good membrane material for optically sensitive, biosensitizing agents. Tricosano-2, 4-dynoic acid (TCDA) and 10, 12-pentacosadiynoic acid (PCDA) were utilized as the matrix lipids and dioctadecyl glycerylether- $\beta$ -glucoside (DGG) as a functional molecule (see pages 101-102). Therefore, these claims are anticipated.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-4, 6-25, 31, 33, 38-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Charych et al. (US 6,303,598).

Charych discloses methods and compositions for the direct detection of analytes and membrane conformational changes through the detection of color changes in biopolymeric materials. In particular, the direct colorimetric detection of analytes using nucleic acid ligands at surfaces of polydiacetylene liposomes and related molecular layer systems (see abstract). In one embodiment, the biopolymeric material comprises self-assembling monomers. In another embodiment, the biopolymeric materials comprise biopolymeric liposomes. "Homopolymers" refers to material comprised of a single type of polymerized molecular species. The phrase "mixed polymers" refers to materials comprised of two or more types of polymerized molecular species (see col. 10 lines 60-64). The term "diacetylene monomers" refers to single copies of hydrocarbons containing two alkyne linkages (i.e. carbon/carbon triple bonds). Liposomes are three-dimensional vesicles that enclose an aqueous space. Liposomes can be constructed so that they entrap materials within their aqueous compartments. Liposomes have the advantages, generally, of making the color change more visually striking and increasing colorimetric response (see col. 23). The self-assembling monomers include diacetylenes (i.e. 5,7-docosadiynoic acid, 5,7-pentacosadiynoic acid and 10, 12-pentacosadiynoic acid). Lipids containing these groups can be homopolymers or mixed polymers. The biopolymeric material may comprise a single species of self-assembling monomer or may comprise two or more species. This mixture is then resuspended in aqueous solution for liposome preparation (see col. 26). Ligands can be covalently linked to the head group of self-assembling monomers (e.g. sialic

acid linked to diacetylene monomers). In another embodiment, carbohydrates, including sialic acid, can be modified. This method provides a means to incorporate a broad range of carbohydrates into biopolymeric material (see col. 55). The liposome finds use as a sensor in a variety of other applications. The color transition of PDA materials is affected by changes in temperature and pH. Thus, the methods and compositions find use as temperature and pH detectors (see col. 66). Therefore, these claims are anticipated.

*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-4, 6-25, 31, 33, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ma Zhanfang et al. (*Acta Physico-Chemica Sinica*) and further in view of Charych et al. (US 6,303,598).

Zhanfang discloses color changeable vesicles of polydiacetylenic matrix incorporating glycolipid based on physical force. Zhanfang does not disclose the polydiacetylene polymer may comprise homopolymers.

Charych discloses methods and compositions for the direct detection of analytes and membrane conformational changes through the detection of color changes in biopolymeric materials. In particular, the direct colorimetric detection of analytes using nucleic acid ligands at surfaces of polydiacetylene liposomes and related molecular layer systems (see abstract). In one

embodiment, the biopolymeric material comprises self-assembling monomers. In another embodiment, the biopolymeric materials comprise biopolymeric liposomes. "Homopolymers" refers to material comprised of a single type of polymerized molecular species. The phrase "mixed polymers" refers to materials comprised of two or more types of polymerized molecular species (see col. 10 lines 60-64). The term "diacetylene monomers" refers to single copies of hydrocarbons containing two alkyne linkages (i.e. carbon/carbon triple bonds). Liposomes are three-dimensional vesicles that enclose an aqueous space. Liposomes can be constructed so that they entrap materials within their aqueous compartments. Liposomes have the advantages, generally, of making the color change more visually striking and increasing colorimetric response (see col. 23). The self-assembling monomers include diacetylenes (i.e. 5,7-docosadiynoic acid, 5,7-pentacosadiynoic acid and 10, 12-pentacosadiynoic acid). Lipids containing these groups can be homopolymers or mixed polymers. The biopolymeric material may comprise a single species of self-assembling monomer or may comprise two or more species. This mixture is then resuspended in aqueous solution for liposome preparation (see col. 26). Ligands can be covalently linked to the head group of self-assembling monomers (e.g. sialic acid linked to diacetylene monomers). In another embodiment, carbohydrates, including sialic acid, can be modified. This method provides a means to incorporate a broad range of carbohydrates into biopolymeric material (see col. 55). The liposome finds use as a sensor in a variety of other applications. The color transition of PDA materials is affected by changes in temperature and pH. Thus, the methods and compositions find use as temperature and pH detectors (see col. 66).

Absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Zhanfang by substituting homopolymers of Charych for the copolymers of Zhanfang because of the expectation of obtaining similar results. Both Zhafang and Charych disclose liposomes comprising diacetylenes, specifically 10, 12-pentacosadiynoic acid. Therefore, one of ordinary skill in the art would expect similar results if the liposomes comprise homopolymers or copolymers as taught by Charych.

11. Claims 1-4, 6-25, 29-31, 33, 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Food Color Facts (USFDA) and in further view of Jo et al. (US 6,277,652)

The USFDA discloses food color facts. A color additive is any dye, pigment or substance that can impart color when added to applied to food, drug, cosmetic or the human body. Additives are known to be added to sauces, gravies, soft drinks, baked good and other foods. Certifiable color additives are used widely because their coloring ability is more intense than most colors derived from natural products. In addition, certifiable colors are more stable, provide better color uniformity and blend together easily to provide a wide range of hues. Certifiable color additives generally do not impart undesirable flavors to foods. Color additives are known to be added to foods because of color variation throughout the seasons and the effects of food processing and storage often require that manufacturers add color to certain foods to meet customer expectations. The primary reasons for adding colors to food include: 1) to offset color loss due to exposure to light, air, extremes in temperature, moisture and storage conditions, 2) to correct natural variation in color, 3) to enhance colors, 4) to provide a colorful identity of foods that would be otherwise virtually colorless, 5) to provide a colorful appearance to certain "fun

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foods", 6) to protect flavors and vitamins and 7) to provide an appealing variety of wholesome and nutritious foods that meet customers' demands.

Jo discloses a colorimetric sensor comprising polydiacetylene membrane liposomes, a polydiacetylene membrane film or fine particles coated with polydiacetylene membrane, in which the polydiacetylene membrane is incorporated with a protein having a reduced molecular weight low enough not to cause color change in the polydiacetylene membrane (see abstract). Diacetylenes, such as 10, 12-pentacosadiynoic acid are disclosed. Jo does not disclose the ingestible to be food.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the food compositions with certifiable dyes disclosed by the USFSA by adding the polydiacetylene membranes liposomes, membranes and coated particles as taught by Jo because of the expectation of offsetting color loss due to exposure to light, air, extremes in temperature, moisture and storage conditions, correcting natural variation in color, enhancing colors, providing colorful identity of foods that would be otherwise virtually colorless, providing a colorful appearance to certain "fun foods", protecting flavors and vitamins and providing an appealing variety of wholesome and nutritious foods that meet customers' demands as suggested by the USFDA .

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

*Correspondence*

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett: RMB  
March 7, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600